


UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,942	12/06/2001	Guriq Basi	ELN-002	5594

959 7590 09/24/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,942	BASI ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63,69,70,72,77-85,114,123,133,137,147,148,151-154 and 157* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-63,69,70,72,77-85,114,123,133,137,147,148,151-154 and 157.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-41 and 62 (in part)**, drawn to a humanized immunoglobulin and pharmaceutical compositions comprising same, classified in class 424, subclass 130.1, for example.

II. Claims **42-48 and 62 (in part)**, drawn to a humanized immunoglobulin and pharmaceutical compositions comprising same, classified in class 424, subclass 130.1, for example.

III. Claims **49-52 and 62 (in part)**, drawn to a humanized immunoglobulin and pharmaceutical compositions comprising same, classified in class 424, subclass 130.1, for example.

IV. Claim **53**, drawn to a chimeric immunoglobulin, classified in class 530, subclass 387.1, for example.

V. Claim **54 and 56**, drawn to an immunoglobulin comprising SEQ ID NO: 5 and SEQ ID NO: 8, classified in class 530, subclass 387.1, for example.

VI. Claim **55 and** 57, drawn to an immunoglobulin comprising SEQ ID NO: 11 and SEQ ID NO: 12, classified in class 530, subclass 387.1, for example.

VII. Claims **58-61 (each in part)**, drawn to a method of preventing or treating an amyloidogenic disease in a patient comprising administering to the patient an effective dosage of the immunoglobulin of Invention I, classified in class 424, subclass 130.1, for example.

VIII. Claims **58-61 (each in part)**, drawn to a method of preventing or treating an amyloidogenic disease in a patient comprising administering to the patient an effective dosage of the immunoglobulin of Invention II, classified in class 424, subclass 130.1, for example.

IX. Claims **58-61 (each in part)**, drawn to a method of preventing or treating an amyloidogenic disease in a patient comprising administering to the patient an effective dosage of the immunoglobulin of Invention III, classified in class 424, subclass 130.1, for example.

X. Claims **63, 69, and 70**, drawn to an isolated polypeptide, classified in class 530, subclass 300, for example.

XI. Claims **72, 77, 78, 79, 80, and 81**, drawn to a method for producing an antibody recombinantly, nucleic acids, vectors, and host cell comprising same, classified in class 435, subclass 69.1, for example.

XII. Claim **82 and 83**, drawn to a method for identifying residues amenable to substitution in a humanized 3D6 immunoglobulin variable framework region and use of the variable region sequence set forth as SEQ ID NO: 2 or 4, or any portion thereof, in producing a three-dimensional image of a 3D6 immunoglobulin, 3D6 immunoglobulin chain, or domain thereof, classification dependent upon method steps.

XIII. Claims **84, 85, 114, and 137 (in part),** drawn to a humanized immunoglobulin and pharmaceutical compositions comprising same, classified in class 424, subclass 130.1, for example.

XIV. Claims **123 and 137 (in part)**, drawn to a humanized immunoglobulin and pharmaceutical compositions comprising same, classified in class 424, subclass 130.1, for example.

XV. Claim **133 (in part)**, drawn to a method of preventing or treating an amyloidogenic disease in a patient comprising administering to the patient an effective dosage of the immunoglobulin of Invention XIII, classified in class 424, subclass 130.1, for example.

XVI. Claim **133 (in part)**, drawn to a method of preventing or treating an amyloidogenic disease in a patient comprising administering to the patient an effective dosage of the immunoglobulin of Invention XIV, classified in class 424, subclass 130.1, for example.

XVII. Claims **147, 148, 150, 152, 153, and 154**, drawn to a method for producing an antibody recombinantly, nucleic acids, vectors, and host cell comprising same, classified in class 435, subclass 69.1, for example.

XVIII. Claim **157**, drawn to a method of identifying residues amenable to substitution in a humanized 10D5 immunoglobulin variable framework region, classification dependent upon method steps.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions VII, VIII, IX, XI, XII, XV, XVI, XVII, and XVIII are

directed to methods that are distinct both physically and functionally, and are not required one for the other.

4. Invention VII requires search and consideration of using the antibody of Invention I as a therapeutic agent, which is not required by any of the other Inventions. Invention VIII requires search and consideration of using the antibody of Invention II as a therapeutic agent, which is not required by any of the other Inventions. Invention IX requires search and consideration of using the antibody of Invention III as a therapeutic agent, which is not required by any of the other Inventions. Invention XI requires search and consideration of recombinant production of antibodies for Invention I, II, and/or III, which is not required by any of the other Inventions. Invention XII requires search and consideration of identifying residues amenable to substitution and three-dimensional imaging for 3D6, which is not required by any of the other Inventions. Invention XII requires search and consideration of determining the presence or amount of a nucleic acid molecule in a sample, which is not required by any of the other Inventions. Invention XV requires search and consideration of using the antibody of Invention XIII as a therapeutic agent, which is not required by any of the other Inventions. Invention XVI requires search and consideration of using the antibody of Invention XIV as a therapeutic agent, which is not required by any of the other Inventions. Invention XVII requires search and consideration of recombinant production of antibodies for Invention XIII and/or XIV, which is not required by any of the other Inventions. Invention XVIII requires search and consideration of identifying residues amenable to substitution for 10D5, which is not required by any of the other Inventions.

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, III, IV, V, VI, X, XIII, and XIV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. None of the Inventions I, II, III, IV, V, VI, X, XIII, and XIV are required, one for the other because they all can be prepared by processes which are materially different from using one another, such as by chemical synthesis, or by isolation and purification from natural sources.

6. Inventions XI and each of I, II, III, and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the antibodies of Inventions I, II, and III as well as the polypeptide of Invention X can be made through a materially different process such as chemical synthesis.

7. Inventions I and each of VII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the antibody of Invention I can be used in materially different process such as immunoassays (*in vitro*) and purification of proteins.

8. Inventions II and each of VIII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention II can be used in materially different process such as immunoassays (*in vitro*) and purification of proteins.

9. Inventions III and each of IX and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III can be used in materially different process such as immunoassays (*in vitro*) and purification of proteins.

10. Inventions X and each of VII, VIII, IX, and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention X can be used in materially different process such as immunoassays (*in vitro*) and purification of proteins.

11. Inventions XIII and each of XV, XVII, and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention XIII can be used in materially different process such as immunoassays (*in vitro*) and purification of proteins.

12. Inventions XIV and each of XVI, XVII, and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention XIV can be used in materially different process such as immunoassays (*in vitro*) and purification of proteins.

13. Inventions I and each of VIII, IX, XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of VIII, IX, XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VIII, IX, XV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention I.

14. Inventions II and each of VII, IX, XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of VII, IX,

XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, IX, XV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention II.

15. Inventions III and each of VII, VIII, XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of VII, VIII, XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, VIII, XV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention III.

16. Inventions IV and each of VII, VIII, IX, XII, XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and each of VII, VIII, IX, XII, XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, VIII, IX, XII, XV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention IV.

17. Inventions V and each of VII, VIII, IX, XII, XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions V and each of

VII, VIII, IX, XII, XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, VIII, IX, XII, XV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention V.

18. Inventions VI and each of VII, VIII, IX, XII, XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of VII, VIII, IX, XII, XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, VIII, IX, XII, XV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention VI.

19. Inventions X and each of XV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of XV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions XV, XVI, XVII, and XVIII do not recite the use or production of the *polypeptide* of Invention X.

20. Inventions XIII and each of VII, VIII, IX, XI, XII, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions of Inventions XIII and each of VII, VIII, IX, XI, XII, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, VIII, IX, XI, XII, and XVI do not recite the use or production of the *antibody* of Invention XIII.

21. Inventions XIV and each of VII, VIII, IX, XI, XII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XIV and each of VII, VIII, IX, XI, XII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII, VIII, IX, XI, XII, and XV do not recite the use or production of the *antibody* of Invention XIV.

22. This application contains claims directed to the following patentably distinct species of the claimed invention: the groups **(a)-(g)** as listed in claim 63.

23. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 63 is generic.

24. If applicant selects Invention X, one species from the *polypeptide* group must be chosen to be fully responsive.

25. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

26. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

27. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

28. This application contains claims directed to the following patentably distinct species of the claimed invention: the groups **(a)-(q)** as listed in claim 72.

29. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 72 is generic.

30. If applicant selects Invention XI, one species from the *nucleic acid* group must be chosen to be fully responsive.

31. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

32. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

33. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

34. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

35. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

36. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
September 17, 2003

Gary d. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600